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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/765,244	10/30/1997	PETER SEIBEL	8484-018-999	5827

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EXAMINER	
LACOURCIERE, KAREN A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/765,244	SEIBEL ET AL.	
	Examiner	Art Unit	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-134* is/are pending in the application.

4a) Of the above claim(s) *105-134* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84-86 and 88-104* is/are rejected.

7)☒ Claim(s) *87* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In response to applicant's phone call regarding the last Office action, the following corrective action is taken. Applicant noted that the last Office action did not address the arguments Applicant provided in response to the rejections of record. These arguments were set forth in the response filed 03-14-2003, rather than the supplemental response filed 09-23-2003, in which Applicant responded to the restriction requirement set forth on 07-28-2003. The Examiner apologizes for the inconvenience and this supplemental Office action is set forth to address Applicant's arguments. Additionally, Applicant should note, some additional deficiencies were corrected in this Office action.

The period for reply of 3 MONTHS set in said Office Action is restarted to begin with the mailing date of this letter.

Election/Restrictions

Applicant's election with traverse of Group I in the paper filed 09-23-2003 is acknowledged. The traversal is on the ground(s) that the search of the invention of both Group I and II would not be a burdensome search because the constructs only differ in structure in that the nucleic acid is linear versus cyclic. This is not found persuasive because the search for each of the inventions of Group I and II would be a separate and distinct search based on the difference in structure of these constructs and, therefore, would be an undue burden.

Applicant's election without traverse of SEQ ID NO:22 in the paper filed 09-23-2003 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.

Claims 105-134 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 09-23-2003.

Chimeric peptide nucleic acids constructs comprising SEQ ID NO:1 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 09-23-2003.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

The substitute drawing for Figure 6B was received on 09-23-2003. This substitute drawing is acceptable.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 86, 90, 91, 94, 95, 96, 102, 103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 86 recites the limitation "partially palindromic". It is unclear what sequences would meet this limitation, for example, does the sequence have to actually comprise a palindrome or could it have "part" of a palindrome (e.g. one half of a palindrome and, therefore, not a palindrome).

Claim 90 is indefinite due to the recitation "amino function". The term "amino function" is not a term of art and it is unclear what would be considered an "amino function". Claims 94, 95 and 96 are indefinite for the same reasons due to dependence on claim 90.

Claim 91 is indefinite due to the recitation "thiol function". The term "thiol function" is not a term of art and it is unclear what would be considered a "thiol function".

Claim 94 is indefinite due to the recitation "localized". It is unclear what the metes and bounds of the term "localized" are, for example, does the linkage group need to occur at the terminus, or would localized encompass any position generally in the area of the terminus, it is unclear what positions are considered "localized" to the terminus, for example, how far from the terminus a linkage can be located and still considered to be "localized" to a terminus. Claim 94 is also indefinite due to the

recitation "hydroxy/phosphate". It is unclear as to whether the linkage group is required to be at a terminal phosphate or hydroxy group. Claims 95 and 96 are indefinite for the same reasons due to dependence on claim 94.

Claim 95 is indefinite due to the recitation "replicative gene". The term "replicative" is not a term of art and it is unclear what type of gene would be considered "replicative", for example, does this mean genes involved in replication, or a gene which has been replicated or capable of being replicated or something else? Claim 96 is indefinite for the same reasons due to dependence on claim 95.

Claim 96 recites the limitation "the promoter" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 102 is indefinite due to the recitation "groupings", as it is not a term of art in the context in which it is being used and the skilled artisan would not know what "groupings" is referring to.

Claim 103 recites the limitation "derivative thereof". It is unclear what kinds of modifications and the degree of modifications could be made to a molecule and have that molecule be considered a "derivative " of m-maleimido-benzoyl-N-hydroxy-succinimide ester, rather than an entirely different molecule. The skilled artisan could not determine what linkage agents would or would not be encompassed in this term and therefore could not determine the scope of the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 92 and 93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendments filed 03-14-2003 have added the limitations wherein the linkage group is bound to the nucleic acid via a spacer comprising at least two carbon atoms (claim 92) or comprising six carbon atoms (claim 93). Applicant has not pointed to any support for these newly added limitations and support for these limitations could not be found in the originally filed specification or claims. To overcome this rejection Applicant should direct the examiner to specific support for these limitations in the originally filed specification or claims or delete these limitations.

Claims 84-86 and 88-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 84-86 and 88-104 are drawn to peptide nucleic acid chimeras which comprise a broad genus of mitochondrial signal peptides, but the specification only

discloses two members of the genus, SEQ ID NO:1 and SEQ ID NO:22, which are both signal peptides directed to the mitochondrial matrix isolated from rats. The specification does not appear to disclose any signal peptides for mitochondrial compartments other than the mitochondrial matrix, nor does the specification provide mitochondrial signal peptide sequences from any species other than the rat. There is no indication in the specification of how to identify or obtain other members of the claimed genus. Due to the variation in structure (i.e. amino acid sequence) among members of the claimed genus, one skilled in the art would not recognize that the applicant was in possession of the necessary common features and attributes of the claimed genus, because the two disclosed signal peptides (from the same species of organism) would not be representative of the claimed genus, which is highly variant.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1 and SEQ ID NO:22, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d

1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 1 and 22 but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The two species

specifically disclosed (i.e. SEQ ID NO: 1 and 22) are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 84-86, 89, 90, 92, 94, 97, 98, 99, 101, 102, 103, and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Vestweber et al.

Vestweber et al. teach a protein DNA conjugate wherein the c-terminal cysteine of the protein is linked to a DNA molecule via an aminoethyl linker group using a heterobifunctional linkage agent (maleimidobenzoyl-N-hydroxysuccinimide). The protein portion comprises a mitochondrial signal peptide (specifically, yeast cytochrome oxidase subunit IV presequence) which has a reactive cysteine at the c-terminus. The nucleic acid portion is linked at the 5'-terminal hydroxyl group and comprises either a double stranded (which comprises two helical turns) or single stranded DNA 24-mer, which contains regions of complementarity so, therefore, the singlestranded DNA may form a hairpin and has secondary structure. The DNA is "partially palindromic", as it comprises the sequence "TAAT", which is a four base palindrome. The DNA conjugate is imported across the mitochondrial membrane using natural transport mechanisms.

Response to Arguments

Applicant's arguments filed 03-14-2003 have been fully considered but they are not persuasive. In response to the rejection of record of claims 1 and 82, under 35 USC 102(b) as anticipated by Vestweber et al., set forth in the prior Office action mailed 07-05-00, Applicant argues that Vestweber et al. does not anticipate the claimed invention because The Vestweber reference is directed to a 24-mer oligonucleotide linked to a mitochondrial precursor protein. Applicant argues that the instant claims are distinguished from Vestweber et al. because the construct disclosed by Vestweber et al. contains a mitochondrial presequence from the yeast cytochrome oxidase subunit IV precursor linked to a mouse modified dihydrofolate reductase protein, but that the claimed constructs do not recite the presence of a dihydrofolate reductase component. These arguments have been considered to the extent that they read on the rejection set forth herein of claims 84-86, 89, 90 and 92 under 35 U.S.C. 102(b) as being anticipated by Vestweber et al. but have not been found to be persuasive.

Although the construct disclosed by Vestweber et al. comprises additional elements not specified in the instantly claimed constructs, the language of the claims is "comprising" and, therefore, is open language and the claims encompass constructs that have additional elements not specified in the claims, including the constructs disclosed by Vestweber et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 84-86, 88, 89, 90-99, 101, 102, 103, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vestweber et al. in view of Williams et al. further in view of Latham et al.

Claims 84-86, 88, 89, 90, 92, 94-99, 101, 102, 103, and 104 are drawn to peptide nucleic acid chimeras which comprise a signal peptide specific to mitochondria.

Vestweber et al. teach peptide nucleic acid chimeras comprising a mitochondrial signal peptide and methods of delivering said chimeras (see rejection under 35 USC § 102).

Vestweber et al. do not teach the specific limitations wherein the nucleic acid portion of the disclosed chimeras comprise phosphorothioate bonds, mRNA's, transcribable genes, replicatable genes and mitochondrial promoters. Vestweber et al.

do not teach linker agents with thiol reactive groups and spacers including 2 and 6 carbon atom spacers.

Williams et al. teach delivery of nucleic acid constructs into a mitochondria in vitro (cell culture), using a signal nucleic acid specific for mitochondria, to introduce genes into mitochondria.

Latham et al. teach phosphorothioate bonds in a peptide nucleic acid chimera and further teach spacers with thiol reactive groups and spacers including 2 and 6 carbon atom spacers.

It would have been obvious at the time the instant invention was made to make a peptide nucleic acid chimera comprising a mitochondrial specific signal peptide, as taught by Vestweber et al., using a nucleic acid which comprises phosphorothioate bonds, mRNA's, transcribable genes, replicatable genes, mitochondrial promoters, because all of the claimed elements would be required to express a gene in a mitochondria, once delivered to a mitochondria, as taught by Williams et al. Further, it would have been obvious to make the nucleic acid portion of the claimed chimera using a phosphorothioate backbone, as taught by Latham et al., to impart greater stability and using liker agents comprising thiol reactive groups and spacers including 2 and 6 carbon atom spacers, as taught by Latham, because linkers of these type where well known in the art and would have been an obvious variant from the type of linker chosen by Vestweber. Phosphorothioate bonds, mRNA's, transcribable genes, replicatable genes, mitochondrial promoters were all well known in the art at the time the instant invention was made and, further, were all well known as a requirement for gene

expression, as suggested by Williams et al. for delivery into mitochondria. One skilled in the art would have been motivated to make a peptide nucleic acid chimera comprising phosphorothioate bonds, mRNA's, transcribable genes, replicatable genes or mitochondrial promoters in order to deliver and express a gene in a mitochondria, in vitro, in order to replace a mutant copy of said gene, as taught by Williams et al. as preliminary investigations (in vitro) for future gene therapy. One would have been motivated to incorporate the phosphorothioate bonds to impart greater resistance to nuclease digestion in order to increase the half life of the nucleic acid in cell culture.

Therefore, the invention of claims 84-86, 88, 89, 90, 92, 94-99, 101, 102, 103, and 104 would have been obvious over Vestweber et al. in view of Williams et al. further in view of Latham et al., absent evidence to the contrary.

Response to Arguments

Applicant's arguments filed 03-14-2003 have been fully considered but they are not persuasive. In response to the rejection of record of claims 25 and 37 under 35 USC 103(a) as being unpatentable over Vestweber et al. in view of Williams et al. further in view of Latham et al., as set forth in the prior Office action mailed January 17, 2001, Applicant argues that there is no teaching in Vestweber et al. that a mitochondria specific signal peptide could direct the entry of an oligonucleotide into mitochondria, nor does Vestweber et al. teach that large nucleic acids such as plasmids could be taken up into mitochondria. Applicant argues that the Williams et al. reference teaches the use of RNA import elements for transport into mitochondria and the elements responsible for the import are sequences within the RNA and that the protein elements attached to the

oligonucleotide are for stability purposes and that Williams et al. is actually teaching using RNA to import proteins, which is a different goal than that of the instantly claimed invention. Applicant argues that the Lantham reference is related to the uptake of oligonucleotides with a conjugated molecule attached, wherein cholesterol is the exemplified embodiment of such molecule and while peptides are listed as possible conjugated molecules, there is no suggestion that these bound molecules would facilitate transport into the mitochondria. Applicant argues that the present invention does not contemplate the use of cholesterol for uptake and, therefore, Lantham is not relevant to the instant invention. Applicant argues that there is no reasonable expectation in the prior art that nucleic acid molecules larger than an oligonucleotide would be imported into cells and be functional, when attached to a mitochondria signal peptide, as claimed.

These arguments have been considered to the extent that they read on the rejection of record set forth herein under 35 USC 103(a), but have not been found persuasive. Vestweber et al. provides specific experiments that demonstrate conjugates of a mitochondrial peptide bound to an oligonucleotide are taken up into cells and the entire reference is directed to import of nucleic acids into cells and the conjugates disclosed by Vestweber et al. are clearly teaching conjugates encompassed within the claimed conjugates, therefore, Vestweber et al. clearly teaches this aspect of the invention. The claims do not require that the claimed construct direct the delivery of a plasmid into a mitochondria, which are directed to compositions and not methods, and wherein the claims do not do not require a plasmid as part of the claimed conjugate. Applicant is arguing a limitation not found within the claims. Williams et al. is not relied upon to teach signal peptides to provide the delivery signal to import nucleotides into the mitochondria, the teaching of that aspect of the invention is supplied by Vestweber

et al., as discussed in the rejection of record. Williams et al. is relied upon to teach the desirability and feasibility of importing nucleic acids which comprise coding sequences, including the specific embodiments of the instant invention, into mitochondria, and it would be obvious to substitute the RNA signal of Williams et al. for the peptide signal taught by Vestweber et al. as discussed in the rejection of record. Lantham et al. exemplifies cholesterol, but additionally suggests peptides for import signals. Lantham et al. is not relied upon in the rejection of record to teach mitochondrial import using peptides, but rather is relied upon to teach phosphorothioate bonds and specific linage agents were well known in the art for use in nucleic acid conjugates for import into cells, the purpose set forth by Vestweber et al. Applicant's argument that there was no reasonable expectation of success for importing large molecules not persuasive because there is no limitation in the claimed compositions that requires the oligonucleotide in the conjugate have a particular size. Applicant is arguing a limitation not found in the claims. Additionally, there is no reason why the skilled artisan would not reasonably expect to be able to make conjugates between the signal peptide taught by Vestweber et al. and a nucleic acid with elements including coding sequences, like those disclosed by Williams et al. Williams et al. demonstrates making peptide nucleic acid conjugates wherein the nucleic acid includes coding elements like those specified in the claims and there is no reason to expect that similar constructs could not be made using the peptide disclosed by Vestweber et al. It would be reasonable to expect that other nucleic acids could be used in the same type of method disclosed by Vestweber et al., regardless of the sequence.

Claim Objections

Claim 87 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any rejection of record not repeated herein is considered to be withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (571) 272-0759. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere
April 9, 2004

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER